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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,480	06/12/2001	Jack C. Whittier	HrdMgmtCIP	6452

7590 04/03/2006

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/879,480		WHITTIER ET AL.	
	Examiner		Art Unit	
	Carla Myers		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,30-40,45,46,49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 30-40, 45, 46, 49, and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/19/04; 1/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed January 27, 2006. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. Claims 28, 30-40, 45, 46, 49 and 50 are pending and have been examined herein. This action is final.

Priority

2. It is noted that the present application is not entitled to the filing date of the provisional applications 60/224,050 and 60/211,093 because these applications do not provide basis for the claimed invention as a whole and in particular do not provide basis for methods of managing a plurality of bovine female mammals for increased economic efficiency in a commercial environment wherein the methods comprise estimating an economic cost of inducing early puberty in female non-human mammals, estimating an economic gain of harvesting substantially all of said nonhuman female mammals, utilizing a time interval wherein the time interval results in a net economic gain and harvesting the nonhuman female mammals upon expiration of a time interval that results in net economic gain and net biological gain.

Information Disclosure Statement

3. The information disclosure statement filed in this application on 12/13/2005 fails to include a concise statement of the relevance of the following non-English language reference listed, as required under 37 CFR § 1.98(a)(3): Ozhin et al (1961); Prokefiev (1983); Solsberry (1966); Wintzer/Van Der Holst (1982); and Van Munster (1999). The above items of information have not been considered by the examiner. Additionally, the

Art Unit: 1634

Pursel et al (1978) reference has not been considered because a copy of this reference was not provided (the record provided consisted of only the citation to Pursel et al). The other items of information that are otherwise in compliance with the provisions of 37 CFR §1.97-1.98 have been considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 30-40, 45, 46, 49 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide basis for the concepts of methods of managing a plurality of bovine female mammals for increased economic efficiency in a commercial environment wherein the methods comprise estimating an economic cost of inducing early puberty in female non-human mammals, estimating an economic gain of harvesting substantially all of said nonhuman female mammals, utilizing a time interval wherein the time interval results in a net economic gain and harvesting the nonhuman female mammals upon expiration of a time interval that results in net economic gain and net biological gain.

The specification as originally filed provides basis for the general concept of a method of managing nonhuman female mammals and in particular provides support for methods which comprise inducing early puberty in a female nonhuman mammal, fertilizing at least one egg in said mammal using a plurality of sex-sorted spermatozoa, producing offspring from said mammal, and harvesting the mammals following the birth of offspring. At pages 12-13, the specification discusses an Integrated Herd Management System (IS) that incorporates reproductive factors such as inducing early puberty, synchronizing estrous, use of sex sorted sperm, and early weaning of offspring. At page 4, the specification teaches that one aspect of the invention is to increase the percentage of female animals available to expand the herd using sex-sorted sperm. It is stated that integrating early-weaning, induction of early puberty and sexed-sorted semen into a single calf heifer system will increase the value of non-replacement heifers and increase profitability. Additionally, the specification (e.g., page 27 and 49) provides an economic analysis of the total income and expenditures recorded per year. Gross revenue/loss and net revenue/loss were calculated. These calculations took into consideration, for example, pregnancy rates, calf survival, feed costs, breeding costs, pasture lease costs, health costs and market price. The specification (page 32) states that "simulations were conducted to evaluate the effect of pregnancy rate and increased calf survival on profitability." Additionally, the specification (beginning at page 43) teaches evaluating carcass characteristics. At page 12, the specification states that "(w)hile Figure 7 provides a specific time line for beef cattle embodiment of the herd management invention, it is understood that (it) is illustrative of the broad variety of

Art Unit: 1634

species of mammal that can be managed in a similar fashion.” However, the cost analysis provided in the specification was performed with respect to the management of bovine.

The teachings in the specification do not provide basis for the specific embodiments set forth in the present claims. The specification teaches estimating the economic costs of inducing early puberty and discusses certain health effects and fertilization effects associated with inducing early puberty. The specification also discusses estimating the economic gain of harvesting the mammals that were bred. The specification does not teach a method of managing female nonhuman mammals based on the concepts of estimating an economic cost of inducing early puberty in female nonhuman mammals, estimating an economic gain of harvesting substantially all of said nonhuman female mammals, utilizing a time interval wherein the time interval results in a net economic gain and harvesting the nonhuman female mammals upon expiration of a time interval that results in net economic gain and net biological gain. As a whole, there is no disclosure in the specification or in the originally filed claims of a method of managing animals which takes into consideration only the cost of inducing puberty and the economic gain of harvesting animals. There is also no disclosure in the specification of a method of managing bovine mammals which determines a time interval that allows for a net economic gain wherein the time interval is determined based on the cost of inducing puberty and the economic gain of harvesting mammals and wherein the time interval is then used to determine when the mammals will be harvested. The specification teaches the use of estimates of economic cost and gain to

Art Unit: 1634

evaluate the integrated herd management system – a system which is based on multiple parameters outside of inducing puberty and the time point of harvesting mammals. There are no teachings in the specification as to how to use the estimates of economic cost and gain for any purpose other than the integrated herd management system. The specification teaches the concept of the time interval between inducing early puberty and harvesting the mammals used for breeding (see, e.g., Figure 7). However, the specification does not teach the specific embodiment of determining a time interval that begins at inducing early puberty and ends at harvesting the mammal used for breeding, wherein the time interval results in a net economic gain and does not teach the step of harvesting the female mammals upon the expiration of this time interval. The teachings in the specification of specific time intervals between inducing early puberty and harvesting were not determined based on a time interval that results in a net economic gain.

RESPONSE TO ARGUMENTS:

In the response filed September 6, 2005, Applicants state that the specification at page 52, line 30 expressly states that the various combinations and permutations of each element may be created and presented to optimize design and performance. The response points to page 5, lines 20-24 as teaching the subject matter of the claimed invention of “to integrate early-weaning, induced puberty or sexed semen into a single-calf heifer system to increase value of non-replacement heifers.” These teachings in the specification have been fully considered. However, these teachings do not provide support for the concept set forth in steps “c”, “d” and “e” of the claims which require

Art Unit: 1634

estimating an economic cost of inducing early puberty, estimating an economic gain of harvesting substantially all of the bovine female mammals, determining a time interval that begins with inducing early puberty and ends with harvesting substantially all of the mammals wherein the time interval results in a net economic gain, and harvesting the mammals at the end of the time interval.

In the response of January 27, 2006, Applicants state that an affidavit by John Schenk has been filed to establish that "one of ordinary skill in the art, reading the specification and relying on such ordinary skill, would understand that the teachings of the specification particularly include the full scope of steps "c", "d", and "e" of claim 28. The declarant is an employee of XY Inc., the exclusive licensee of the present patent application. The 132 Declaration of John Schenk has been fully considered but is not persuasive to overcome the present grounds of rejection. The declaration states that with respect to step "c", this concept is explained at page 1, lines 18-30 of the specification wherein it is taught that in order for a SCH system to remain economically sustainable, the end product must be acceptable to the consumer. The declaration concludes that the specification teaches that "a target age of harvest for SCH may be less than 24 months of age in order to minimize the risk of financial discounts and provide the consumer with a highly palatable product." However, while the specification teaches that inducing early puberty will allow for the harvesting of bovine at an early age and that early harvesting of mammals may provide a financial benefit, these teachings do not provide support for the specific concept of evaluating the economic cost of inducing early puberty and then utilizing this economic cost to determine a time interval

Art Unit: 1634

between inducing early puberty and harvesting mammals to achieve a net economic gain. The declaration states that support for step “d” is also found in the teachings of the specification at page 1 in which the specification teaches harvesting at or prior to 24 months. The declaration concludes that “(t)his fact of harvesting to a stricter standard than USDA guidelines evinces the affirmative nature of setting a time interval.”

However, it is unclear as to how the declaration draws such a conclusion. The specification does not include a teaching regarding determining a time interval between inducing early puberty and harvesting that results in a net economic gain. Regarding step “e”, the declaration points to page 2 of the specification as teaching that “a production system in which a SCH is to rear a calf and be ready for harvest by 24 months of age may be accomplished by breeding the heifer at a non-traditional age of 9 months. The fact of breeding a heifer at such a non-traditional age evinces the affirmative nature of determining a time interval.” It is further stated that since the goal of the system is to harvest a mammal at an early age and to take into consideration the economic ramifications of breeding at an early age, these are teachings “evinced the affirmative nature of determining a time interval.” However, again, it is unclear as to how this conclusion has been reached. A teaching in the specification of the benefit of inducing early puberty and harvesting a mammal at an earlier age is not equivalent to a teaching of determining a time interval between inducing early puberty and harvesting a mammal that results in a net economic gain and harvesting the mammal at the end of this time interval. No factual evidence has been provided to support the opinions set forth in the declaration. In particular, no evidence has been provided to support the

Art Unit: 1634

opinion that the teachings in the specification regarding the induction of early puberty in order to allow for the harvesting of mammals at an earlier age and the desire to obtain an economically favorable system provide support for the claimed subject matter of estimating an economic cost of inducing early puberty, estimating an economic gain of harvesting substantially all of the bovine female mammals, determining a time interval that results in a net economic gain and which begins with inducing early puberty and ends with harvesting substantially all of the mammals, and harvesting the mammals at the end of the time interval.

Further, as discussed in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977), "(e)ntitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. See Martin v. Mayer, 823 F.2d 500, 504, 3 USPQ2d 1333, 1337 (Fed. Cir. 1987) (stating that it is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure Rather, it is a question whether the application necessarily discloses that particular device.") (quoting Jepson v. Coleman, 314 F.2d 533, 536, 136 USPQ

Art Unit: 1634

647, 649-50 (CCPA 1963)). ... One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. Id. ("[T]he applicant must also convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba, see Eiselstein v. Frank, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) ("[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims"), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient."

In summary, the teachings in the specification that it is beneficial to harvest a mammal at 24 months of age and that to do so could be accomplished by inducing early puberty and breeding the mammal at 9 months of age does not provide specific support for the concept of steps "c", "d" and "e". Throughout the specification numerous other parameters are evaluated as to their effect on economic gain and cost and these parameters are also taken into consideration in context with the cost and effect of the parameters of sex-sorting sperm and using sex-sorted sperm for artificial insemination. However, the claims do not recite that the management system takes each of these parameters and economic costs and gains into consideration. Further, the individual

Art Unit: 1634

teachings of inducing puberty and obtaining an economic gain by harvesting mammals at an age to produce a high quality carcass does not provide support for the concept of a system based on an economic analysis of only the cost of inducing early puberty, the economic gain of harvesting mammals, the determination of a time interval between inducing early puberty and harvesting mammals that results in a net economic gain and the harvesting of mammals at the expiration of said time interval.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS FILING OF AN INFORMATION DISCLOSURE STATEMENT AFTER FIRST ACTION (see MPEP 706.07(a)):

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 31, 32-40, 45, 46, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riggs (Thesis, Spring 2000; cited in the IDS of 1/27/2006).

Riggs teaches a method for managing a plurality of bovine female mammals for increased economic efficiency. The reference (page 2) states that a single-calf heifer (SCH) production system in which cows are ready for harvest at 24-months of age can be accomplished by breeding the cows at 9-months of age. It is further stated (page 2) that "if a SCH could produce only female calves, then only one parturition per female would be necessary and the dam could be slaughtered at a young age to still attain

Art Unit: 1634

consumer acceptability without maturity discounts, thus creating a self-perpetuating system. " It is also stated that to accomplish early breeding, induction of early puberty is necessary. In particular, at page 28, the reference teaches that MGA can be used to both induce early puberty and synchronize estrous. At page 35, the reference cites Hohenboken as teaching that inseminating young cows with sexed semen may yield female progeny that have reduced calving difficulties and increased calf survival. The reference (page 40) also states that "by calving at an age younger than 24 months, sexed-semen to yield female progeny would decrease risk of incidence and severity of dystocia. In addition, this technology carries the benefit of creating the opportunity to create a self-perpetuating SCH system." Riggs also teaches performing an economical analysis for each step in the management system and particularly for the use of insemination with sex-sorted semen (see, for example, pages 32-33 and 37). Riggs (page 73) concludes that "(t)he integrated system in which early-weaning and sexed-semen are incorporated into the single-calf heifer system, is an accelerated system that allows one calf to be born to a heifer targeted for slaughter at 24-mo of age. The IS depends on achieving an early puberty allowing a IS heifer to be bred at 10-mo of age...If a high reproduction rate can be achieved and calf mortality kept to a minimum, great profitability can be achieved over selling non-replacement heifers immediately following weaning at a traditional age."

Riggs (see, e.g., the abstract) exemplifies methods of managing female bovine mammals which comprise artificial insemination of the early weaned bovine with sex-sorted sperm at 10-months of age and harvesting of the mated bovine at approximately

Art Unit: 1634

24 months of age (i.e, 719 ± 12.7 days) and teaches that the economical analysis of each step of the management system. Riggs does not specifically exemplify a method of managing female bovine in which one estimates the cost of inducing early puberty in the female bovine, estimates the gain of early harvesting the mated female bovine, induces early puberty in the bovine, fertilizes at least one egg of the bovine using sex-sorted semen, and harvests substantially all of the mated bovine at a time interval that results in a net economic gain wherein the time interval begins at the time of inducing early puberty and ends at the time of harvesting. However, Riggs does teach each of these elements of the ISH system and specifically teaches the advantage of inducing early puberty, the advantage of breeding at 9-months of age, the advantage of harvesting at 24 months of age and the advantage of using sex-sorted sperm to generate a self-perpetuating female bovine population. Further, Riggs teaches that each phase of the system should be evaluated for its economic cost and gain.

In view of the teachings of Riggs, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have generated a system of managing female bovine in which one estimates the cost of inducing early puberty in the female bovine, estimates the gain of early harvesting the mated female bovine, induces early puberty in the bovine, fertilizes at least one egg of the bovine using sex-sorted semen, and harvests substantially all of the mated bovine at a time interval that results in a net economic gain wherein the time interval begins at the time of inducing early puberty and ends at the time of harvesting. One would have been motivated to have done so because Riggs teaches that the steps of inducing early puberty, mating the

Art Unit: 1634

mammal at an early age (e.g. 9-10 mo) and harvesting the mammal at an early age (e.g, 24 mo) are economically advantageous and provide a quality end product to the consumer.

With respect to claims 31 and 45, Riggs (page 47) teaches inseminating the bovine with 3 million frozen-thawed sperm, which is considered to be about half the dosage of a typical unsexed insemination sample.

With respect to claim 32 and 36, Riggs (page 2) teaches that the bovine can be breed at 9 to 10 months of age.

With respect to claim 33, Riggs (page 45) teaches that to induce early puberty, bovine were fed 1.36 kg/day until they began to cycle.

With respect to claims 34 and 35, Riggs (page 50) teaches early weaning of bovine offspring at approximately 120 days.

With respect to claims 37-38, Riggs teaches (page 46) teaches synchronizing the bovine at 250 ± 15 days by dressing feed with 0.5mg of MGA per day for 14 days followed by PGF2 injections 19 days after the MGA feeding.

With respect to claims 39 and 40, Riggs (e.g., page 73) teaches harvesting the mated bovine at approximately 24 months.

With respect to claim 46, Riggs (page 63) teaches that 69% (i.e., "about 70%") of the offspring from the bovine inseminated with sex sorted semen were female.

With respect to claim 49, Riggs teaches replacing each of the bovine in a self-perpetuating system (see, e.g., page 2).

With respect to claim 50, Riggs (page 47) teaches producing offspring in a single parturition.

6. Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Riggs in view of Seidel (Theriogenology. 1997, 48: 1255-1264; cited in the IDS)

The teachings of Riggs are presented above. Riggs teaches insemination of the bovine with frozen sperm, but does not teach insemination of the bovine with non-frozen sperm.

However, Seidel (e. g, page 1257) teaches successful artificial insemination of bovine with 100,000, 250,000, live, unfrozen sex-sorted sperm (see the table therein).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Riggs so as to have inseminated the bovine with 500,000 live sex sorted sperm, in place of frozen sperm, in instances in which unfrozen sperm was available, in order to have avoided any problems associated with freezing and thawing of sperm and to thereby have provided an effective means for artificially inseminated the female bovine.

Applicant's filing of an Information Disclosure Statement necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1634


mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
March 29, 2006


CARLA J. MYERS
PRIMARY EXAMINER